Controlled Copy No.....

The Ipswich Hospital NHS
NHS Trust

ELECTRO-MEDICAL ENGINEERING
ISO 9001:2000
QUALITY ASSURANCE MANUAL

QUALITY ASSURANCE MANUAL DISTRIBUTION LIST

Copy Name/Number	Location
Master	Estate & Facilities
Controlled Copy 1	EME Workshop
Controlled Copy 2	Quality Manager
Controlled Copy 3	X-Ray Engineer
Controlled Copy 4	Internal Auditor

AMENDMENT RECORD SHEET

Date	Amendment No.	QP	Comments	Amendment Carried Out By	Sign.

Quality Policy

It is the policy of the Electro-Medical Engineering (EME) Dept. to provide an economic, reliable and efficient service.

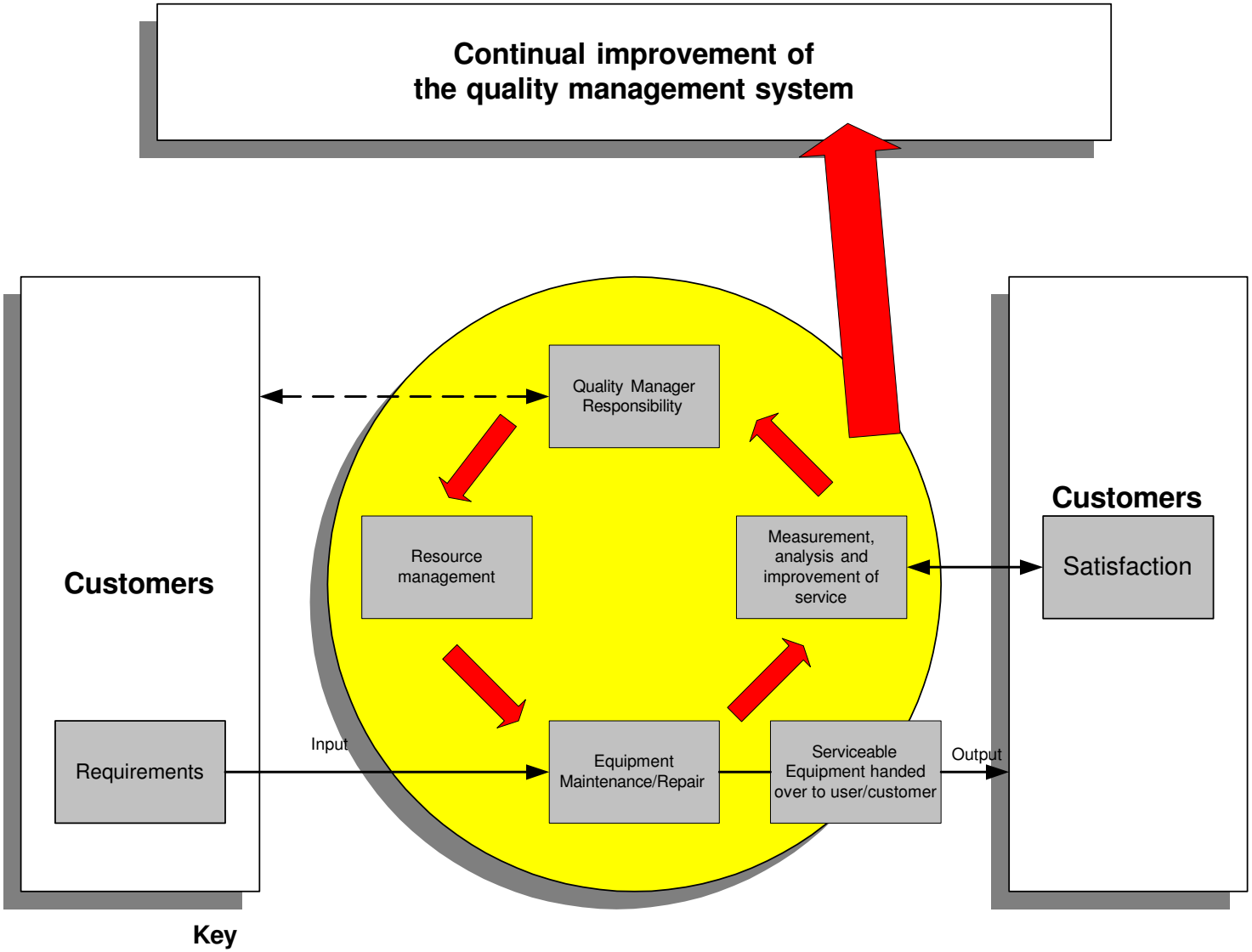
The EME Dept. will maintain a level of satisfaction as required by the customers whilst conforming to the quality objectives and requisite statutory and regulatory requirements.

The EME Dept. is committed to complying with requirements of the customer and ISO 9001:2000 and to continually improving the effectiveness of the quality system.

Quality improvement objectives are established, pursued and reviewed by senior management at regular intervals.

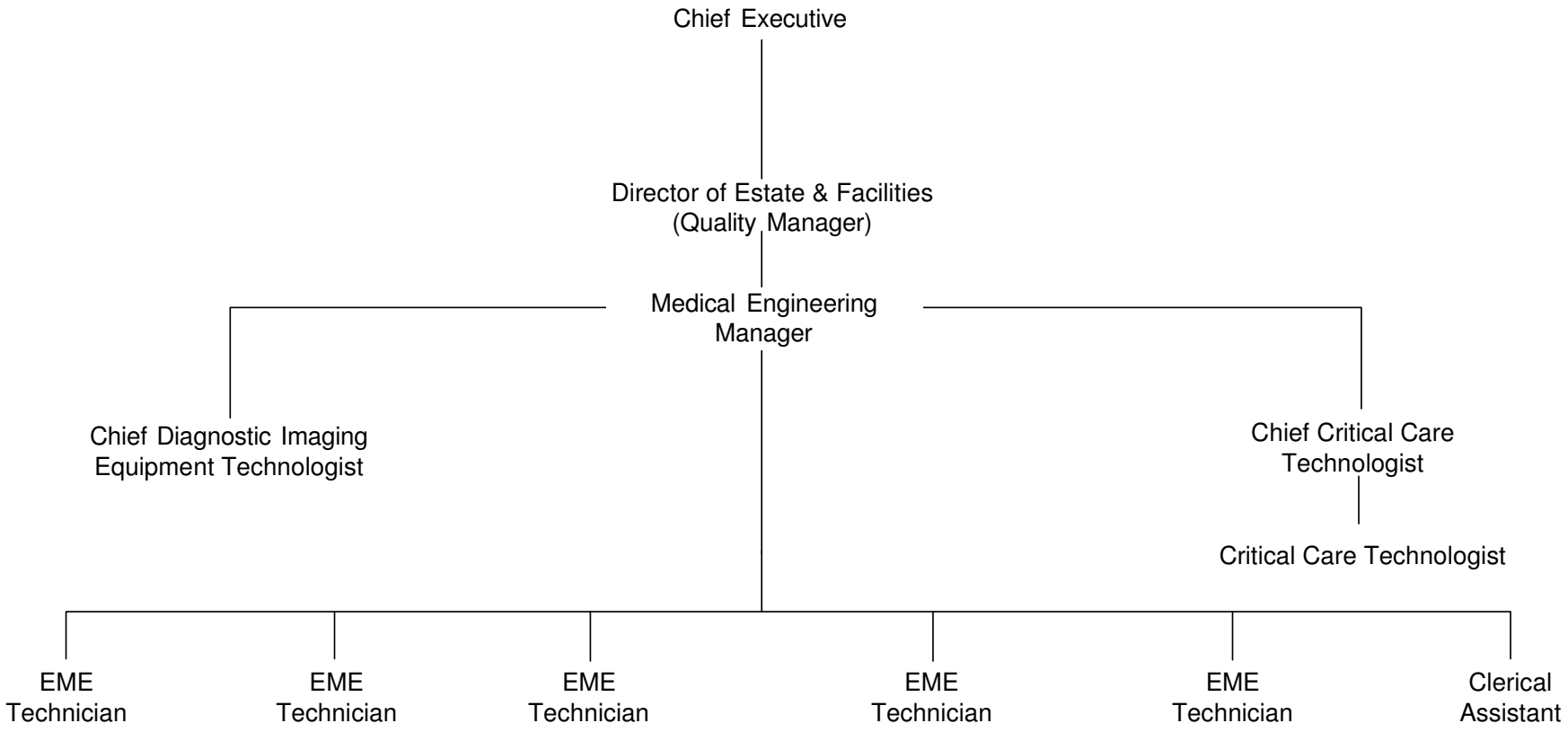
Management ensure that this policy is communicated, understood and implemented at all levels within the organisation, and that it is reviewed annually for continuing suitability.

…….
Andrew Reed
Chief Executive
The Ipswich Hospital NHS Trust



Model of a process-based quality management system

The Ipswich Hospital NHS Trust
Estate & Facilities
Electro-Medical Engineering Organisational Structure



Quality Manual

The Ipswich Hospital NHS Trust

ELECTRO-MEDICAL ENGINEERING

ISO 9001:2000

The scope of the quality management system:
The corrective and preventative maintenance of electro-medical and x-ray equipment.

Details of and justification for any exclusions: Design and development (ISO 9001:2000 para 7.3) is excluded from our Quality Management System because all product and service is manufactured and delivered in accordance with customer specifications and instructions.

Servicing / Maintenance

Receive Call / Equipment

Raise Task Sheet

Attach Label to Equipment

Test / Repair

SABs Outstanding

Final Inspection Test

Complete Job

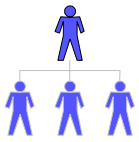
Attach Job Completed Label

Complete Documentation

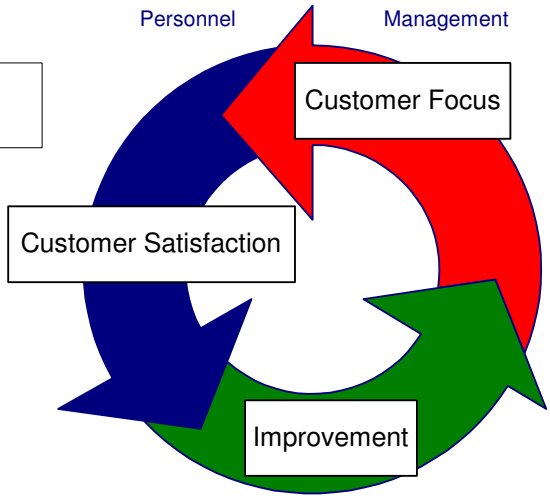
Return to Department / Customer

Feedback

Personnel



Management



Quality Assurance

Purchasing

CUSTOMER SATISFACTION DATA

Quality Objectives

Internal Audit

Resource Managment

Improvement& Data Analysis

Quality Assurance

QP01 Control of Documents
QP02 Control of Records
QP15 Control of NC
QP05 Corrective Action
QP06 Preventative Acion
QP07 Internal Audit Reports

Procedures

QUALITY OBJECTIVES FOR ISO9001 : 2000

The following objectives have been agreed by the Management of the EME Department in accordance with the criteria set within ISO9001:2000. These objectives will be reviewed at the Management Review Meetings and intermittently in the interim if deemed necessary.

Objective 001:	To computerise the stores system.		
Action:		**Completed By:**	**Responsibility Of:**
1.	Install Network points at all work benches	Immediate action	EME Manager
2.	Install computers at all work benches	March 04	EME Manager
3.	Choose the software that will be used	April 04	EME Manager and all technicians
4.	Install the software onto all computers	April 04	EME Manager
5.	Transfer data from cards onto software	May 04	EME Manager and all technicians
6.	Start using software instead of cards	June 04	EME Manager and all technicians

Action	Status	Date	Initials
1.	Completed.	Nov 03	P.H.
2.	Completed.	Feb 04	P.H.
3.	Completed.	Feb 04	P.H.
4.	Completed.	March 04	P.H.
5.	Completed.	April 04	P.H.
6.	Completed.	April 04	P.H.

Objective 002:	To reduce average job completion times by 5%		
Action:		**Completed By:**	**Responsibility Of:**
1.	Sample current jobs to assess current response times.	Dec 2003	EME Manager
2.	Analyse the current system to be able to formulate an action plan	Jan 2004	EME Manager and Quality Manager

Action	Status	Date	Initials
1.	Complete.	Nov 04	P.H.
2.	Complete.	Nov 04	P.H.

Objective 003:	To improve condemning notification to include more people (item brought up in feedback from wards)		
Action:		**Completed By:**	**Responsibility Of:**
1.	Assess current system	Dec 2003 Revised = Mar 05	EME Manager and Quality Manager
2.	Find out who should be notified and how for all areas	Feb 2004 Revised = Mar 05	EME Manager and Quality Manager
3.	Design new system	Mar 2004 Revised = Apr 05	EME Manager and Quality Manager
4.	Rewrite procedure if required	April 2004 Revised = May05	EME Manager and Quality Manager
5.	Implement new system	May 2004 Revised = Jun 05	EME Manager and Quality Manager

Action	Status	Date	Initials
1.	Complete	Mar 05	P.H.
2.	Complete	Mar 05	P.H.
3.	Complete	Apr 05	P.H.
4.	Complete	Apr 05	P.H.
5.	Complete	Apr 05	P.H.

Objective 004:	To investigate, and set-up if required, a user discussion forum.		
Action:		**Completed By:**	**Responsibility Of:**
1.	Ask a small sample of users if a forum would be useful, and what format they believe it should take	April 05	EME Manager
2.	Analyse the sample results	May 05	EME Manager and Quality Manager
3.	Decide if a forum would be suitable and what format it should take.	June 05	EME Manager and Quality Manager
4.	Set-up and start the forum	Aug 05	EME Manager and Quality Manager

Action	Status	Date	Initials
1.	Completed via phone poll	May 05	P.H.
2.	Completed	May 05	P.H.
3.	Decided that a regular forum would not be beneficial, possibility of '1 off' forums in the future.	May 05	P.H. & V.B.
4.	Action not taken	May 05	P.H.

Objective 005:	To redesign the repair requisition form		
Action:		**Completed By:**	**Responsibility Of:**
1.	Set up a technician meeting to produce a sample form	May 05	EME Manager
2.	Ask for feedback on sample form from users	June 05	EME Manager and Quality Manager
3.	Analysis feedback and redesign form if required	Aug 05	EME Manager and Quality Manager
4.	Produce new form and put into use.	Oct 05	EME Manager and Quality Manager

Action	Status	Date	Initials
1.	Done by individual meetings - Complete	Nov 05	P.H.
2.	Complete	Dec 05	P.H.
3.	Complete	Dec 05	P.H.
4.	Complete	Jan 06	P.H.

Objective 006:	Investigate possible methods for reducing PPQ paperwork		
Action:		**Completed By:**	**Responsibility Of:**
1.	Analyse current method used	Feb 06	EME Manager
2.	Search for suitable alternative methods	May 06	EME Manager
3.	Analyse alternative methods for effectiveness and suitability	Jul 06	EME Manager
4.	Decide which method should be used.	Sep 06	EME Manager and Quality Manager

Action	Status	Date	Initials
1.	Complete	Feb 06	P.H.
2.	Complete	May 06	P.H.
3.	Complete	Jul 06	P.H.
4.	Complete	Aug 06	P.H. & S.H.

Objective 007:	Analyse current Electro-Surgical Diathermy test equipment for suitability with current equipment located in Theatres.		
Action:		**Completed By:**	**Responsibility Of:**
1.	Ascertain current test equipment's functionality	Apr 06	EME Manager
2.	Ascertain requirements of equipment located in Theatres	Jul 06	EME Manager
3.	Analyse if requirements match functionality	Nov 06	EME Manager
4.	Report on any gap in requirement with recommendations	Jan 07	EME Manager

Action	Status	Date	Initials
1.	Complete	Apr 06	P.H.
2.	Complete	Jul 06	P.H.
3.	Complete	Oct 06	P.H.
4.	Complete	Dec 06	P.H.

Objective 008:	Put into place new PPQ method of paperless working.		
Action:		**Completed By:**	**Responsibility Of:**
1.	Ascertain best method of scanning in current paper PPQ's	Oct 06	EME Manager
2.	Find location to store and backup scanned PPQ files	Dec 06	EME Manager
3.	Add functionality to PPQ database to be able to view scanned PPQ files	Feb 07	EME Manager
4.	Scan in PPQ's and add them to the database	May 07	EME Manager

Action	Status	Date	Initials
1.	Complete	Oct 06	P.H.
2.	Complete	Nov 06	P.H.
3.	Complete	Jan 07	P.H.
4.			

Index Of Procedures

Title	QP No:	QA Standard No:
Document Control	QP01	4.2.3
Quality Records	QP02	4.2.4
Training	QP03	6.2.2
Customer Complaints	QP04	7.2.3 / 8.2.1
Corrective Action	QP05	8.5.2
Preventive Action	QP06	7.2.1 / 8.5.3
Internal Quality Audits	QP07	8.2.2
Production Identification and Traceability	QP08	
Handling Procedure for MOS	QP09	
Procedure for the provision of Radiation Protection and Image Quality Services	QP10	
Condemning Procedure	QP11	
Decontamination Procedures	QP12	
Goods Inward Procedure	QP13	
Control of Non Conforming Product	QP14	8.3
Stock Controls and Storage	QP15	
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Procedure for Purchase of Services	QP17	
Procedure for Purchase of Goods	QP18	7.4.1 / 7.4.3
Inspection and Test Status	QP19	
Procedure for Planned Preventative Maintenance	QP20	
Process Control	QP21	
AntiStatic Workstation Calibration Procedure	QP22	
Inspection Measuring and Test Equipment	QP23	

DOCUMENT CONTROL

DOCUMENT APPROVAL AND ISSUE

1. During maintenance activities the EME and X-Ray section uses a number of documents, circuit drawings, etc (see table 1). Copies are kept at the location where needed, e.g. EME and X-Ray workshops. Procedures are carried out to ensure that obsolete documents are destroyed or marked to avoid confusion. All reference documents are amended to ensure that they are up to date.

2. The Quality Manager in conjunction with the Medical Engineering Manager has the responsibility to approve documents for adequacy prior to issue and for the issue of all quality documents and work procedures. All members of staff are responsible for maintaining complete sets of documents issued to them which are essential for their work. It is also the responsibility of the members of staff to incorporate such amendments to documents which they receive.

3. Maintenance will be carried out to the equipment manufacturer's instructions detailed in the service manual. Where this is not available other documentation will be used.

4. All documentation referred to in "1" above are to be clearly marked by a distinctive stamp or label to indicate one of the following:

   Master
   Copy
   Obsolete

5. A log is to be maintained of all master documents with a record kept on it of all amendment dates.

6. All reference documents shall be kept current. Any changes or modifications or amendments shall be carried as detailed in “DOCUMENT CHANGES/AMENDMENTS” below.

7. All master documents shall be kept secure in a dry controlled environment designated as the technical library.

8. Members of staff will inform the Medical Engineering Manager of any documents that are becoming illegible or are not easily identifiable.

DOCUMENT CHANGES/AMENDMENTS

11. As changes to documents become necessary they should be done to a set procedure and checked by authorised staff. When amendments are complete the master log also needs to be updated. In the case of extensive amendments the whole document may be reissued.

12. The Quality Manager in conjunction with the Medical Engineering Manager has responsibility for authorising and issuing amendments to documents. It is the responsibility of all members of staff to incorporate any amendments which they receive into their working copies.

13. Reference documentation is maintained at latest issue by the Quality Manager, as far as is practicable.

14. All members of staff must keep documented work procedures in their possession up to date with all authorised amendments.

15. If at any time a member of staff believes a change to be necessary in a work practice he must bring the matter to the attention of the Medical Engineering Manager.

16. The Medical Engineering Manager will review the merits of the change and will authorise a further change where necessary.

17. In cases where the amendments are extensive the document may be reissued; on receipt all old copies must be destroyed.

18. As amendments are made, documents reissued, etc all these changes are to be entered on the master log sheet.

19. Principle external standards employed by the EME department are British standards and Medicines and Healthcare products Regulatory Agency (part of the Department of Health)

10. The BSI standards are updated monthly due to the department subscribing to the ‘PLUS’ service.

11. MDA updates and re issues are sent automatically to all acute hospitals in the UK.

TABLE 1 CONTROLLED DOCUMENTS MASTER LIST

Document	Location
Manufacturers' service manuals (EME)	Tech. library
Manufacturers' service manuals (X-Ray)	X-Ray Workshop
BS EN 60601-1 (BS 5724) Medical equipment, part 1	Tech. library
BS EN 60601-1 (BS 5724) Medical equipment, part 2	Tech. library
2.25 Specification for servo-controlled infant incubators	Tech. library
2.119 Specification for baby incubators	Tech. library
2.120 Specification for transport incubators	Tech. library
2.121 Specification for infant radiant warmers	Tech. library
2.3 Specification for short wave therapy equipment	Tech. library
2.14 Specification for electro-convulsive therapy equipment	Tech. library
2.22 Specification for general operating tables	Tech. library
2.23 Specification for oxygen concentrators	Tech. library
2.24 Specification for humidifiers	Tech. library
2.4 Specification for cardiac defibrillators and monitors	Tech. library
2.5 Specification for safety of ultrasonic therapy equipment	Tech. library
ISO 9001:2000 Quality systems	Tech. library
HEI 98 Management of equipment	Tech. library
HEI 95 Code of practice for acceptance testing for medical equipment	Tech. library
DHSS A comparative evaluation of medical carbon dioxide laser systems 1986	Tech. library

Document	Location
DHSS Register of approved manufacturers 1990	Tech. library
Eshle	Tech. library
Quality assurance guidelines for mammography NHSBSP	X-Ray Workshop
TRS 89	X-Ray Workshop

QUALITY RECORDS

1. To demonstrate that the quality assurance system as stated in the quality manual is operating effectively, quality records need to be set up and maintained. This procedure deals with who is responsible for the records set up by the procedures, how they are stored and how they are accessed.

2. The Quality Manager is responsible for stating which officers are responsible for which records and to define which records need to be maintained.

3. All records shall be kept in such a way as not to deteriorate over the period of time which they are expected to be retained, e.g. out of sunlight and damp conditions.

4. Records which have to be maintained are detailed in Table 2, together with the officer who is designated to maintain the records.

5. Records shall be kept for a period of 5 years unless otherwise stated.

6. When records are kept on a computer database the person responsible for its upkeep shall regularly back up the system.

7. Records shall be kept in a legible, neat and orderly way with such information entered as is required.

8. When stated in a contract, records shall be made available for inspection by a client.

TABLE 2 QUALITY RECORDS

Record	*Location*	*Responsible Officer*
Task sheet	EME Workshop	Medical Engineering Manager
Repair requisition	EME Workshop	Medical Engineering Manager
PPM computer job lists	EME Workshop	Medical Engineering Manager
Asset request sheet	EME Workshop	Medical Engineering Manager
Invoice/service reports	Office	Medical Engineering Manager
Defect and failure reports	EME Workshop & Office	Quality Manager
Customer Complaints	Office	Quality Manager
Indemnity records	EME Workshop	Medical Engineering Manager
Warranty repairs	EME Workshop	Medical Engineering Manager
Training records	Office	Quality Manager
Audit of workshop standards	Office	Quality Manager
Calibration certificates	EME Workshop	Medical Engineering Manager
Quality audit reports	Office	Quality Manager
Substandard suppliers	Office	Quality Manager
Condemned equipment	EME Workshop	Medical Engineering Manager
Goods inward documentation	EME Workshop	Medical Engineering Manager
Back-up disks (asset records)	Office	Quality Manager
Minutes of management review meetings	Office	Quality Manager

TRAINING

1. It is realised that to operate an effective quality system together with an efficient department, high quality staff correctly trained to meet the demands of the EME/X-Ray division is of prime importance. The following outlines a system to accomplish this objective.

2. The responsibility for training rests with the Quality Manager who determines what level of skill is required to fulfil the EME/X-Ray function. Training requirements are discussed by the Medical Engineering Manager and the Chief Diagnostic Imaging Equipment Technologist who make recommendations to the Quality Manager. In-House training is the responsibility of the Medical Engineering Manager and Chief Diagnostic Imaging Equipment Technologist.

3. As the work of Estate and Facilities EME/X-Ray section is of a high technical level, staff are required to have a minimum of ONC/BTEC or equivalent at entry, or in the case of apprentices, to work towards that level.

4. As most of the equipment to be maintained is in a hospital environment all new staff are required to attend the hospital induction course which is a one-day internal course where general issues and aims of the health service are described, together with basic fire, infection control and manual handling precautions.

5. It is attempted to send all new members of staff who are not specifically EME technicians at entry, on a 2-week general electro-medical course where instruction is given on the use and operation of many commonly found types of electro-medical equipment. When this is not possible, senior members of the EME staff take on this responsibility.

6. Information is sought from equipment manufacturers on the availability of service courses on specific equipment. As it is deemed necessary selected technicians attend those courses which the Quality Manager judges most beneficial to the service.

7. Once the Technician returns, they are asked for feedback on the course, and they are supervised at a later date to assess their competency. The results of this will be taken into the Management Review Meeting.

8. A method has been established whereby "on site training" is provided by the manufacturer's service personnel. During this training a set of working manuals are constructed by the X-Ray technicians. Where such training requires extra resource, this will be made available by the Quality Manager. These working manuals are kept in the X-Ray workshop and are revised as necessary when changes/modifications are implemented.

9. All apprentices receive a basic training at the local EITB approved training centre prior to joining the EME full time. On joining the division each apprentice is given tasks commensurate with their ability and they are closely supervised by senior staff. These tasks form part of an approved EITB schedule to which the Quality Manager is their coach. Academic work is towards obtaining a BTEC certificate.

10. A training record is maintained on all technicians. All certificates are copied and put in the technicians personnel file. These records are compiled by the Quality Manager, the purpose of which is to access the present and future training requirements of the organisation.

11. Training is part of the management review meeting, where the training needs of the individual are accessed together with the service requirement of the organisation. Training courses that have taken place will also be reviewed at these meetings. Decisions made at these meetings are implemented as soon as finance/staff levels permit, e.g. to send a technician on a training course.

CUSTOMER COMPLAINTS AND FEEDBACK

Complaints

1. It is the responsibility of all technicians who receive any complaints concerning the department to inform the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist. Complaints should be in a written format (letter or e-mail), if any other form of complaint is received (i.e. by phone, or in person) they will be asked to make the complaint formal by putting it in writing. Records are to be maintained by the Quality Manager.

2. All complaints will be documented on a customer complaints form. This is filled in by the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist.

3. All documentation is held by the Quality Manager, who will also inform the complainant of action which is to be taken.

4. Once a decision has been made about the complaint, the Quality Manager will inform the complainant of the action to be taken, and any reasons for this. The response of the complainant will be taken to the Management Review Meeting to assess whether the action was effective.

Feedback

1. When feedback is obtained it is the responsibility of the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist to document the feedback and it's source, complete with the process that the feedback was given in, i.e. during a phone call, or a visit to/from a customer etc.

2. It is the responsibility of the Quality Manager to ensure that the received feedback is analysed and any necessary action is carried out. Records are to be maintained by the Quality Manager.

CORRECTIVE ACTION

1. Prompt action to correct reported faults is essential for both the operation of the quality system and to maintain customer confidence. Thus the causes of such faults should be investigated and documented, unless trivial in nature where documentation would be uncalled for. If a change to a working method has been deemed necessary, checks must be made to ensure compliance.

2. The Quality Manager is responsible for monitoring all non-conforming products, customer complaints and actions taken to rectify them. The Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist, in addition to remedying complaints, must review the reliability of the equipment that they maintain. All the above topics are discussed at the Management Review Meetings.

3. The Quality Manager will closely monitor all forms relating to non-conformance, condemning, reject customer complaints, warranty, SAB Bulletins, etc. He will review these on a regular basis with the view to improvements to be implemented.

4. Such action as is considered necessary to correct a non-conforming product/service shall be carried out by the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist or a technician under his supervision.

5. When a course of action is decided upon by the Quality Manager, he will take such steps as are necessary to check on its implementation.

6. All such issues shall be recorded at the Management Review meetings, to enable timely action to be taken to prevent recurrence of non-conformances.

PREVENTIVE ACTION

1. Every effort shall be made to take preventive action once it has been identified.

2. Work operations are clearly detailed in the original manufactures service instructions for customer's equipment.

3. Prior to the purchase of new equipment, the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist will request that a service/maintenance manual is ordered (if required), when PPQ's are provided by the Procurement Dept.

4. Other sources of information such as manufactures revision sheets, or service action bulletins etc will be acted upon.

5. When equipment has been sent away for repair, the technician will scrutinise the service report for preventive measures that could be taken or are recommended.

6. Customer complaints and feedback will be analysed and acted upon.

7. The results of the internal audits shall be acted upon to an agreed timescale.

8. Training courses and tools shall be made available for equipment that requires specialised or in-depth resources, or where increased technician knowledge would be preferable to work on the equipment.

9. All such preventive action will be discussed at the Management Review Meetings.

INTERNAL QUALITY AUDITS

1. At intervals it is necessary to undertake an audit of the various sections of the quality system to verify that department activities comply with the stated arrangements as laid down in the Quality Manual. After an audit the results will be reviewed and action taken where necessary.

2. The appropriate officer shall undertake the quality audit. The choice of responsible officer is made by the Quality Manager.

3. Quality audits shall be carried out at regular intervals as indicated in the audit plan, the frequency being decided by the Quality Manager on the basis of its status and importance.

4. Quality audits may be carried out at any other frequency as the Quality Manager considers necessary to meet the contingencies of the service.

5. Notice will be given to the section concerned of audit dates.

6. Quality audits are conducted to verify that the quality system is being used, that it is being adhered to and that it is effective as a quality tool.

7. Suitable training shall be given to staff who undertake such quality audits.

8. These audits are carried out by staff independent of the activity being audited.

9. Audit reports and any resulting non-conformity reports will be produced and stored electronically in a spreadsheet format.

10. A copy of the audit report will be sent electronically to the person in charge of the operation being audited.

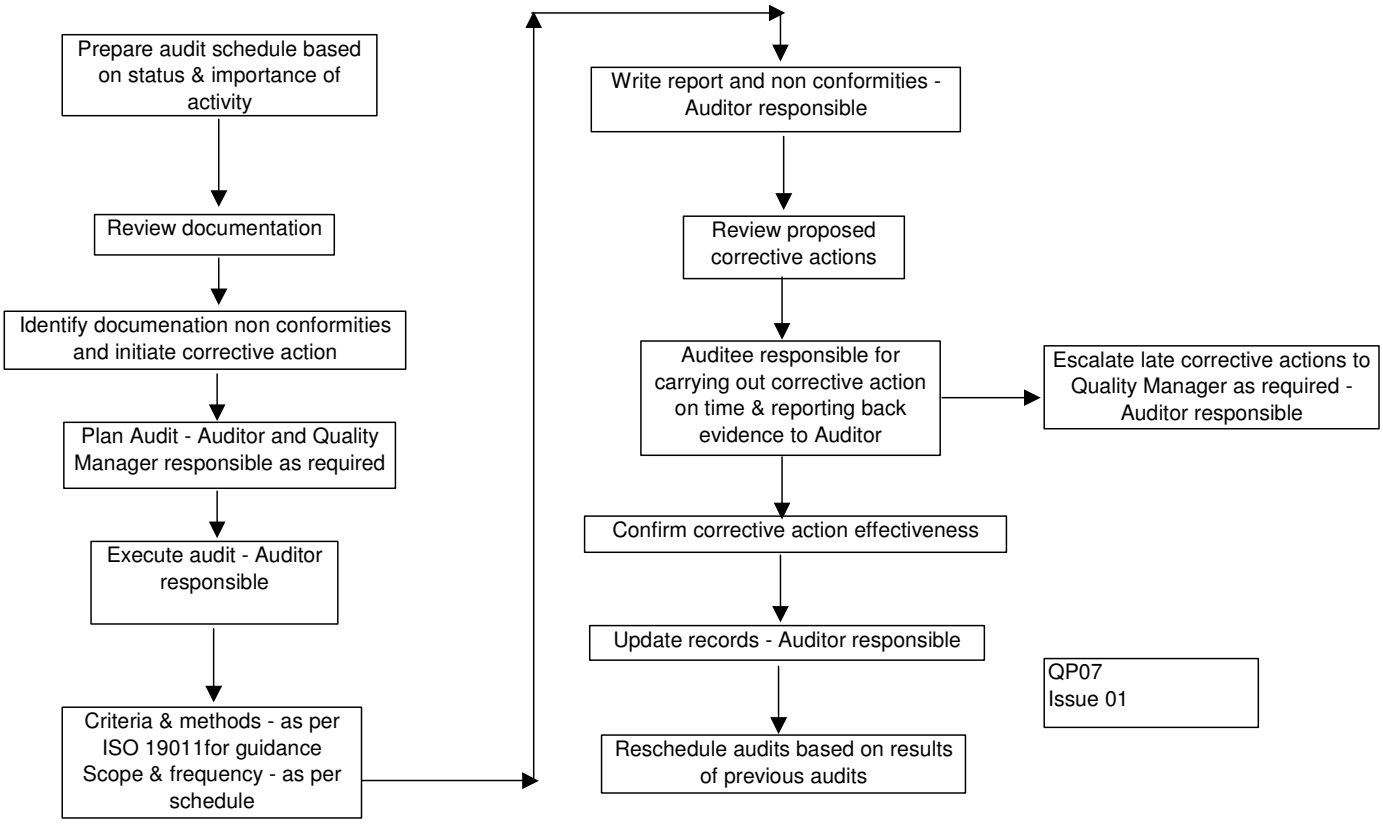
11. Non-conformity reports will be sent electronically to the person in charge of the operation being audited together with a recommended timescale for corrective action to be carried out.

12. Corrective action effectiveness will be evaluated & verified by the auditor, to included follow-up audits as required.

TABLE 1 **AUDIT PLAN**

Section	**Frequency**
Quality Management System	12 Monthly
Management commitment, Customer focus, Quality policy, Planning	12 Monthly
Responsibility, authority & communication	12 Monthly
Management Review & Planning	12 Monthly
Resources incl training	12 Monthly
Infrastructure & work environment (incl safety & maintenance)	12 Monthly
House keeping	12 Monthly
Customer related processes (contract review)	12 Monthly
Purchasing	12 Monthly
Product & Service Provision (Production)	12 Monthly
Calibration & tool maintenance	12 Monthly
Customer satisfaction, Internal audit	12 Monthly
Monitoring & Measurement & NC Product	12 Monthly
Data Analysis & Improvement	12 Monthly

Audit Procedure



QP07
Issue 01

PRODUCTION IDENTIFICATION AND TRACEABILITY

1. All equipment in the control of the department requires to be clearly identified during all stages of work.

2. The Quality Manager is responsible for the overall level of identification. Individual technicians are responsible for ensuring equipment which they are working on is correctly labelled. The Medical Engineering Manager and Chief Diagnostic Imaging Equipment Technologist oversee this task and are also responsible for identification of all incoming goods.

3. All equipment which is worked on shall have a legible asset label firmly affixed. Where this is not the case, one should be affixed. This does not include consumable items.

4. A task sheet shall accompany each item of equipment to be worked on.

The Ipswich Hospital NHS Trust
EME Department

HANDLING PROCEDURE FOR MOS

1. Many items of modern equipment contain MOS type components, which are sensitive to static and may be destroyed by careless handling. The following procedures should be observed to limit damage:

2. All technicians must exercise the utmost care in the handling and storage of static sensitive components and assemblies.

3. Static sensitive components such as integrated circuits when received by the department should be left in the anti-static packing in which they arrived.

4. All static sensitive components and PCBs shall be stored in suitable anti-static bags or boxes.

5. When static sensitive PC boards are worked on, an anti-static workstation shall be used.

6. Soldering irons and tools used in such operations should be briefly touched to earth prior to touching the PCB or component.

7. Technicians working at the workstation should wear an earthed wrist strap. (Via 1 m ohm resistor for safety.)

8. Static sensitive PC boards should be left in their protective anti-static bags until just before being required.

9. Similar action should be taken with components which should be left in their packing for as long as possible.

PROCEDURE FOR THE PROVISION OF RADIATION PROTECTION AND IMAGE QUALITY SERVICES

1. This procedure details the way in which radiation protection and image quality are addressed in the Ipswich Hospital NHS Trust.

2. Procurement of these services are authorised by the Chief Diagnostic Imaging Equipment Technologist in consultation with the Superintendent Radiographer and departmental Radiation Protection Supervisor.

3. Image quality assessment and radiation protection service is provided by the East Anglian Regional Radiation Protection Service based in Cambridge.

4. The local radiation protection advisor is based at Ipswich Hospital, Medical Physics Department, and is used to advise on safety aspects of the equipment on fitting of a new tube or commissioning of a new X-Ray installation.

5. Frequency of checks (region)

    a. Every 12 months, or when requested by the Chief Diagnostic Imaging Equipment Technologist.

    b. Mammography unit - every 6 months.

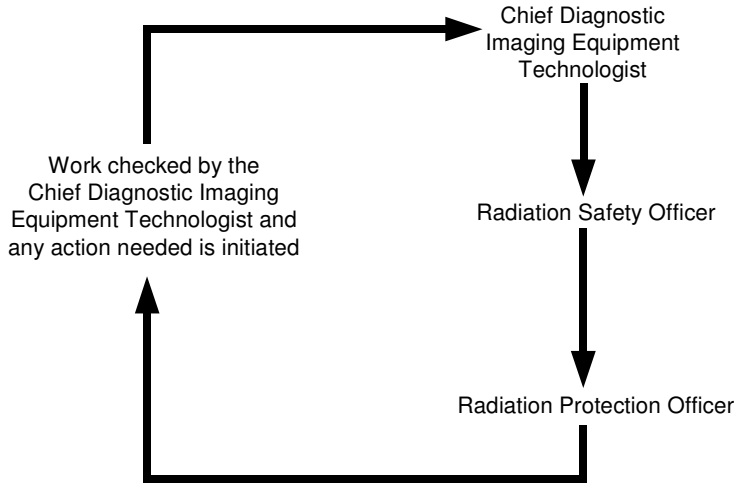
    c. Note - Radiographers send test films for assessment at regular intervals.

6. All checks are done to documented procedures.

7. Reports are sent to the Chief Diagnostic Imaging Equipment Technologist, who retains a copy.

8. Any non-conformances which are apparent in the reports are acted on by the Chief Diagnostic Imaging Equipment Technologist or manufacturer.

9. The procedure for requesting the services of the radiation protection advisor (Ipswich Hospital) is shown below:



X-Ray Unit Locations
Central X-Ray
Woolverstone X-Ray
A & E
Breast Screening
School of Radiography
Felixstowe Gen. Hospital
Aldeburgh Hospital
Outlying Dental Clinics

The Ipswich Hospital NHS Trust
EME Department

CONDEMNING PROCEDURE

1. Equipment which is returned to the department for repair which is subsequently found to be either not repairable or not economic to repair is subject to the following condemning procedure.

2. Note; this applies only to equipment owned by the Ipswich Hospital; in other cases the customer is informed of the situation.

3. The Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist, with the approval of the Quality Manager, shall decide as to whether an item is to be condemned.

4. A decision shall be made as to whether to condemn an item of equipment on the following considerations.

    a) Not repairable
    b) Spares not available
    c) Uneconomic to repair

5. The decision to condemn is taken by Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist in consultation with the Quality Manager.

6. The directorate responsible for the equipment is informed that the equipment should be condemned and are advised to proceed as per 'Equipment Asset Disposal' of the Estates and Facilities Policies. The basis of this procedure is to seek permission from the Director of Finance prior to the disposal of an asset.

7. The item must not be disposed of until permission is granted by the Director of Finance. If the equipment is stored in EME it must be clearly labelled and segregated from other equipment for repair.

8. When permission is given to dispose of the equipment all labels are removed, the equipment made unusable and then located in the skip for disposal off site.

The Ipswich Hospital NHS Trust
EME Department

DECONTAMINATION PROCEDURES

1. As most of the equipment handled by the EME/X-Ray section comes from a medical environment, precautions need to be taken by staff for the control of infection risk from contaminated equipment.

2. All technicians are responsible for their own protection by the use of suitable protective clothing, goggles, etc. The workshop manager is responsible for ensuring such items are available. The Quality Manager monitors the procedures and decides overall policy in consultation with the Control of Infection Officer.

3. Items which are received with a declared infection risk shall be quarantined in a sealed plastic bag and safety isolated. Guidance will be sought from the control of infection officer as to the best course to pursue. Such equipment shall not be worked on until it is deemed safe to do so.

4. As general policy it is the responsibility of the user to ensure that equipment for repair is clean and free from contamination.

5. Some equipment however must be assumed to be contaminated and suitable precautions taken, e.g.

    a. Blood gas analyser
    b. Chiropody drills
    c. Dental equipment

6. The most commonly used personal protection is the use of disposable gloves, and all technicians have access to supplies of such; goggles and respirator masks are also issued.

7. An area of the workshop is set aside for dirty work procedures and should be used for this purpose. Also an exhaust cabinet is provided for use where toxic-noxious gases/dusts are present in cleaning process, e.g. Chiropody drills.

8. All technicians will pay great attention to personal hygiene and wash hands after completion of each task, all cuts and abrasions shall be covered and no food eaten while working.

GOODS INWARD PROCEDURE

1. All incoming goods with the exception of stationery are subject to inspection on receipt by the department. This is to ensure conformity with the order specification and to check that goods are in an acceptable condition.

2. It is the responsibility of the Medical Engineering Manager and Chief Diagnostic Imaging Equipment Technologist to supervise the goods inward procedure, so as to facilitate the efficient working of the system.

3. All goods subject to the goods inward procedure shall be entered into the goods Inward book on receipt. Where relevant, details are entered.

Inspection Sequence

1. External packing examined for damage.

2. Check quantity, type of items against order and examine visually.

3. Check all documentation is correct

4. Clear documentation

5. Repack goods or transfer to stores area.

Inspection of Packing

6. External packing shall be carefully examined, any signs of damage, cuts, dents, rips, etc shall be brought to the attention of the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist.

7. All goods inwards are visually examined to determine correct quantity and to identify any obvious damage.

8. 100% sampling is carried out on any batch less than ten similar items.

9. Any defects are notified to the Medical Engineering Manager or Chief Diagnostic Imaging Equipment Technologist.

Document Accuracy

10. Original order documentation should be compared with the delivery/advice note to check they concur.

11. Does the item need special storage?

12. Does the item have a shelf life?

13. Is delivery on time?

Rejection of Goods

1. Goods which are found not to comply with the goods inward procedure are rejected, and the following steps taken:

2. Goods are labelled, "Faulty", tie on label or similar to include date, order number and technician.

3. Non-confirming product form, made out - note made in Goods Inwards book.

4. Note of reason for rejection is made on order form - order is not cleared.

5. Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist decides on action to take.

Clearing Paperwork and Goods

Goods

1. Where there are items needing individual identification they are thus marked, e.g. Major sub-assembly to be held in stores.

2. Items requiring repacking are carefully repacked.

3. Goods such as repaired items and new equipment requiring testing and logging in to the system are clearly labelled with a status label. A task sheet is made out and the item put into the Tasks In area.

4. All other stores items are dealt with in accordance with stores procedures.

Paperwork

5. The advice/dispatch note is dated and filed.

6. The official order is signed off and returned to treasurers - copy kept in EME/X-Ray.

CONTROL OF NON-CONFORMING PRODUCT

1. As a service/maintenance department, examples of non-conforming products would be sub standard servicing, faulty spares or equipment.

2. Any faulty spare parts which are identified shall be returned to the supplier with documentation stating what the part is, and what the fault is. A copy of this documentation shall be filed by the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist.

3. Equipment which is still within the warranty period that is provided by the supplier, and is found to be faulty, shall be returned to the supplier for repair. Documentation stating what the equipment is, and what the fault is shall be included in the packaging. A copy of this documentation shall be filed by the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist.

4. Equipment which is not repairable is normally scrapped. The condemning document is filled out by the technician, and is passed on to the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist. The equipment is placed in the quarantine area before being made safe, and disposed of after receiving the condemning reference number from the Estates Department.

STOCK CONTROLS AND STORAGE

1. The EME/X-Ray section operations are of a diverse nature and subsequently call for a wide spectrum of spares to be maintained. These must be held in an orderly and secure manner.

2. The Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist is responsible for the efficient operation of stores/ordering in their areas. All technicians are responsible for bringing to the attention of the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist, items which are at re-order level.

3. Stores shall be held in designated areas and where possible in special stores containers, e.g. plastic bins.

4. General storage handling procedure is as described in QP17 Handling, Storage, Packaging and Delivery.

5. Stock should be held at a suitable height to allow safe withdrawal, i.e. heavy items are not to be kept on the top shelf.

6. Environmental conditions in the stores areas shall be controlled to prevent degradation of the stored items.

7. Stored items shall not be in direct sunlight and strong magnetic fields are to be avoided.

8. Temperature shall generally be controlled between 5℃ and 30℃.

9. Stores areas shall only be accessible to authorised staff.

Stock Control

1. All stock shall be clearly marked; in most cases this is by a code on the drawer /bin front which is references from a card index system. Larger items shall be directly marked by tie-on labels etc.

2. Note: Do not use stick-on labels or others that may damage the product finish.

3. Where required by contract, stock shall have the batch number attached to allow traceability.

4. Space shall be allocated in the stores area for the quarantine of stock items; such items shall be segregated from good stock and clearly labelled.

5. Consideration shall be given to the quantity of any item of stock to be held, as too high a stock level is expensive in both space and cost. The following points should be considered before arriving at a stock level.

    i. Rate of stock usage
    ii. Urgency of response, e.g. high for critical equipment
    iii. Availability and delivery from stockist
    iv. Price
    v. Shelf life
    vi. Expected life of equipment

6. Manufacturers' items of stock shall be kept in the main stores area in a bin system, which has coded fronts. The index to these stores is a card index system, held in manufacturers' alphabetical order, sub-divided for equipment types. Each card has details of parts held, present levels of stock and re-order level. On use of an item the stock level is amended and on reaching the re-order level the item is put on the re-order list (held close to the card index).

7. General items such as resistors, capacitors, etc are held in drawer rack systems, which have numbered fronts. The index is a numerical chart with descriptions of drawer contents. As these items are consumables, and can be replaced locally at short notice if needed, the stock replacement level is held to be zero.

HANDLING, STORAGE, PACKAGING AND DELIVERY

The equipment handled by the EME/X-Ray Section is frequently of a delicate medical electronic nature of very high cost. Consequently every care must be taken to ensure its safety whilst in the care of the department.

HANDLING

1. The method employed within the department for handling of equipment shall at all times be such as to avoid damage or deterioration of the product. Care should also be taken not to mix known quality items with ones of unknown quality, e.g. used spares.

2. All technicians are responsible for good handling methods. The Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist shall monitor such activities.

3. Work areas should be clean and tidy prior to commencing work on any equipment.

4. Where static sensitive components or sub-assembly is used, anti-static precautions shall be employed.

5. All items shall be protected from inclement weather conditions when in transit outside.

6. When equipment is moved the status label shall be checked to confirm correct status.

7. Suitable transport shall be used to move equipment to guard against damage, whether in a car or on a trolley.

8. Should the equipment be contaminated it shall not be handled by EME/X-Ray staff until safe to do so.

STORAGE

1. Store areas shall be secure and of a controlled environment to prevent degradation of the equipment.

2. Suitable storage areas are made available by the Estate and Facilities Directorate. It is the responsibility of the Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist to organise the system of storage.

3. Storage of old obsolete equipment such as ECG monitors, test gear, etc. is to be kept to a minimum. All such items are to be labelled.

4. Storage areas shall be tidy and the environment kept within set parameters.

5. All static sensitive products shall be stored in special packing and boxes.

6. Repaired equipment awaiting delivery shall be stored in the tasks out area.

7. Quarantined items shall be clearly marked and segregated from other items.

STORAGE OF ITEMS WITH A SHELF LIFE

1. Certain items used by the department have a limited shelf life so a system has to exist to prevent undue wastage or installation of inferior stock.

2. Goods which have shelf life marked on the package shall have this clearly marked on the label, i.e. the *Use By* date on the label.

3. Other items known to have a shelf life but not marked on the package shall be clearly marked with a *Use By* date on the label.

4. Goods found to be passed the *Use By* date shall be scrapped, unless they have a very limited availability.

5. Review shall be made regularly of item/quantities of shelf life items kept by the section.

6. Where prompt delivery by suppliers can be obtained, e.g. fuel cells, stock shall not be kept.

PACKING

1. All items requiring packing, such as equipment to be returned to the manufacturer for repair, shall be packed with suitable packing in a secure way, preferably using the original manufacturer's material where available.

TABLE 1 **TYPICAL SHELF LIFE**

Batteries	Zinc Oxide	12 months
	Manganese Alkaline	18 months
	Mercury	18 months
	Lithium	12 months
Fuel Cells	Typically . . .	1 to 3 months

DELIVERY

2. The department has a responsibility to ensure that the equipment in its care is delivered to the user/customer in good condition. Special care should be taken when equipment is to be delivered to outside hospitals.

3. All technicians are responsible to ensure that equipment quality is maintained until final delivery. The Medical Engineering Manager shall monitor this procedure.

4. All delivered items shall have passed final inspection and test, results of which shall be recorded on the task sheet.

5. All delivered items that have been repaired shall have a ‘user warning’ label attached where required.

6. Every care shall be taken in the transport of equipment to final destination to avoid damage.

PROCEDURE FOR PURCHASE OF SERVICES

1. This procedure details the clerical aspects of the procedure for purchase of services relating to equipment repair etc.

2. Procurement of services may be authorised by the Medical Engineering Manager or his deputy. All orders are vetted by the Quality Manager. The Medical Engineering Manager or his deputy shall complete all necessary documentation.

3. Orders relating to a purchase of services for the repair of an item of equipment are initiated by the technician controlling the repair. The order is generated in the workshop using the EROS system.

4. The order shall have the following minimum information:

    a. Delivery address
    b. Full description of the item(s) to be repaired
    c. Name and address of the company
    d. Date required

5. On completion of the order the copies are designated thus:

    a. Top copy (white) with the equipment to manufacturer
    b. Bottom copy (white) to Finance
    c. Pink/Yellow are retained in the EME workshop

6. After completion of all documentation the equipment is packed securely complete with the top copy of the order.

7. The package is despatched by wither post or courier dependant on size-weight, a record is kept of this despatch and the article is generally insured.

8. On arrival of the repaired item it is checked off against the order and undergoes goods inward procedure.

9. The delivery note is dated and filed.

10. The service report is inspected and filed.

11. On receipt of the invoice the official order may be cleared with details of cost/date/invoice number entered on the pink copy (retained by EME). The yellow copy is forwarded to the Procurement Department.

PROCEDURE FOR PURCHASE OF GOODS

1. All purchasing is done using the EROS system that is supplied by the Procurement department.

2. Emergency orders are still placed by using the EROS system, but if an order number cannot be obtained within the required time, the requisition number can be used by quoting “REQ-----“ where ---- is the requisition number. If the requisition number cannot be obtained, then the order number “EME999” will be used. Once the official order number is obtained the technician who placed the order must inform the supplier, and the Medical Engineering Manager.

3. The order shall have the following minimum information:

    a. Delivery address
    b. Full description of the item(s) including part number(s)
    c. Name and address of the company
    d. Date required

4. On completion of the order the copies are designated thus:

    a. Top copy (white) to manufacturer
    b. Bottom copy (white) to Finance
    c. Pink/Yellow are retained in the EME workshop

5. On arrival of the goods they are checked off against the order using the goods inward procedure.

6. The delivery note is dated and filed.

7. The Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist will then, following EROS procedure, close the order so that any invoices can be paid by Creditors.

Recommended Suppliers

1. The recommended supplier for spare parts and repairs will be the Original Equipment Manufacturer (OEM).

2. Where the OEM cannot be located, then a supplier can be used based on previous experience, or recommendation from the Procurement department.

3. All recommended suppliers will be monitored for the service that they provide, and this is reported at the regular Management Review Meetings.

INSPECTION AND TEST STATUS

1. At all times when equipment is in the care of the department it must be clearly labelled so as to indicate its status, e.g. awaiting repair. Also, at the completion of a job, the person carrying out the final test/inspection shall sign off the task sheet.

2. Each individual technician is responsible for labelling equipment they receive. Equipment shall be labelled immediately on arrival at the workshop. Incoming equipment shall also be labelled on arrival by the accepting technician. The Medical Engineering Manager is responsible for ensuring rejected, quarantined and condemned equipment is both correctly labelled and stored.

3. All equipment in the care of the department shall have a status label attached to it, suitably marked as required.

4. Results of final inspection/tests shall be recorded on the task sheet which is signed by the technician on completion of the inspection.

5. On completion of final tests/inspection labels shall be affixed to indicate its status, e.g. Tested, Rejected, etc.

6. Large fixed equipment repairs such as X-Ray units; indication of repair in progress shall be displayed at the door to the room for the duration of the repair.

7. Prior to return to the department after service/repair a label shall be attached, which warns of the need to check controls, etc.

PROCEDURE FOR PLANNED PREVENTATIVE MAINTENANCE

1. Planned preventative maintenance (PPM) is work done to a predetermined schedule, the function of which is to reduce the need for corrective maintenance by improved reliability of the equipment. The following procedure is to ensure that the work progressed in an orderly and controlled manner.

2. Planned preventative maintenance tasks shall be assigned to individual technicians by the workshop manager. The technicians have the responsibility for assuring the work is completed satisfactorily and the results recorded. The Medical Engineering Manager shall ensure that the PPM schedules are adhered to.

3. The PPM schedule shall be allocated by the Medical Engineering Manager, in consultation, where applicable, with the customer. Possible frequency being 3, 6 or 12-month intervals.

4. The manufacturer's PPM work schedule shall be followed where there is one available.

5. Where no manufacturer's schedule exists, then an advice note reference 39, which has been approved by the Quality Manager, will be followed.

6. In cases where neither PPM schedule or advice note exist, basic functional checks, plus electrical safety checks to IEC60601-1, shall be performed.

7. All equipment that is subject to PPM is entered on to the PPM programme installed on the department computer.

8. PPM Job lists are allocated to individual technicians who after ensuring they have the necessary tools, manuals and documentation to complete the PPM tasks.

9. Results obtained on PPM visits are entered in the space provided on the job lists (a list of standard entries appears in table 1). Note: Due to the diverse nature of X-Ray equipment and its associated maintenance, the Chief Diagnostic Imaging Equipment Technologist has a different system for recording PPM tasks. No ‘paper’ task

10. sheet is raised. Task description/results are stored digitally in a spreadsheet, maintained by the Chief Diagnostic Imaging Equipment Technologist, and are not fed back into the EME computer system. Additionally, each X-Ray room contains a logbook where all PPM maintenance tasks are recorded after they have been carried out. The logbooks provide a ‘hard copy’ back up for the information held digitally.

11. Completed job lists are returned to the workshop manager prior to their being 'fed back' in to the computer history.

12. Any faults found on PPM visits unless very trivial shall not be done at that time but rather entered as a repair task to be dealt with later.

13. In the event of any item of equipment not being found during a PPM visit, an entry of ‘Not Found’ will be made on the PPM task sheet. A memo will be sent to the relevant head of department to notify them of this situation. When the item of equipment has been located it should be returned to the EME Dept. for PPM prior to use.

14. All technicians should make themselves aware of any local rules in force at the PPM location, e.g. laser safety.

15. On completion of PPM tasks all equipment shall be left in a clean and tidy condition with controls in a safe position, and a tested label affixed indicating the date and technician.

16. In the event of any equipment being found to be unsafe and NHS property, it shall be rendered inoperative. e.g. Mains plug removed and the department equipment controller informed.

17. In the case of a private customer the technician shall strongly advise that the equipment be made inoperative. The Quality Manager shall be made aware of such action and will confirm the advice in writing.

TABLE 1

PPM job list completion	Equipment condition and job list message.
Equipment seen to be in use, cannot disconnect to test.	Job sheet entry - IN USE -
Equipment inspected function/electrical tests all OK.	Job sheet entry - PPM OK e.g. of results - M = 20/25 P = 10/15 B = 0.15 INS = INF
Equipment double insulated or battery operated all OK.	Job sheet entry - PPM OK
Equipment inspected found to be faulty.	Job sheet entry - PPM FAIL TASK SHEET REF…….
Equipment not found.	Job sheet entry - NOT FOUND
Equipment not in use. i.e. stored but not condemned:	Job sheet entry - NOT IN USE Action: Render equipment safe. e.g. remove main plug. Attach label to state contact EME department prior to using the equipment.
Equipment had been calibrated.	Job sheet entry - CALIBRATED PPM OK

All the above messages to be written in the 'Add info' space on the job list, any other comments for EME use are to be written elsewhere, these other comments are not entered on 'feed-back'.

Explanation of electrical results.

M = Electrical leakage, mains to earth microamps forward/reverse.

P = Electrical patient leakage to earth microamps forward/reverse.

B = Earth continuity - ohms.

INS = Insulation resistance - Megohms.

PROCESS CONTROL

1. Procedures to cover the complete range of operations of the department are dealt with in this section. Such tasks as: Planned preventative and corrective maintenance together with acceptance testing are addressed. Standards for acceptance and rejection are clearly stated.

2. Where a new process is envisaged and no procedure exists which is suitable, one will be devised and approved by the Quality Manager.

3. Individual technicians are responsible for the quality, safety and professionalism of their own work. The Medical Engineering Manager and Chief Diagnostic Imaging Equipment Technologist together with the Quality Manager shall define standards of workmanship required and also the issue of any working procedure to be followed.

4. Parts or materials used in service or repair will be obtained from reputable suppliers. Sub-standard suppliers shall not be used unless no other alternative can be found.

5. Spare parts shall be held in the stores area in accordance with stock control system. Levels of stock kept will depend on the numbers of equipment used requiring such items.

6. Traceability of material and parts to the original manufacturer shall be maintained where necessary.

7. All documents, manuals and drawings used in the section shall be kept up to date.

8. Work practices described in the Quality Manual, shall be adhered to.

9. Any change to a work procedure deemed necessary shall be notified to the Medical Engineering Manager.

10. All work performed by EME/X-Ray technicians shall be to a good safe standard.

11. All test/inspection equipment used by the department shall be suitable for its intended use and calibrated where required.

12. Any equipment that uses batteries, which is required to be stored for any length of time, shall have such batteries checked for deterioration, etc prior to storing. If storage is likely to be for an extended period then the batteries should be removed.

13. All battery powered equipment shall have the charge level checked prior to despatch to the client and if necessary replaced.

14. Any information made available to the EME/X-Ray Section in the course of their work shall be treated in strict confidence and not disclosed to a third party.

15. All portable electrical medical and laboratory equipment shall be tested in accordance with IEC60601-1 for electrical leakage and safety. The results of such test are recorded on the task sheet. Equipment shall not be released until these tests have been completed.

16. No food or drink is to be consumed at the workbench while work is being carried out.

17. No smoking is allowed on the Trust site.

<u>Procedure – Acceptance</u>

1. All items maintained by Estate & Facilities EME/X-Ray section shall be allocated a unique asset number, details of which are held on computer.

2. The Medical Engineering Manager/Chief Diagnostic Imaging Equipment Technologist is responsible for ensuring that all new items of equipment are allocated a valid asset number at the acceptance stage. The Asset Manager shall keep this register up to date by suitable entries and deletions to the WIMS database system.

3. On acceptance checks being carried out as per IEC60601-1, an asset request form is made out. This has details of equipment, manufacturer, etc.

4. The Asset request form is passed onto the Asset Manager who will produce an asset ID that it unique to that piece of equipment. The Asset label and asset form are also produced and passed back to the department.

5. The asset label is affixed to the equipment, and the Asset form is placed with the equipment to be returned to the user.

6. Prior to ordering, medical questionnaire forms (PPQ) are received by the department from the supplier/manufacturer. After perusal of the PPQ, a judgement is made whether to recommend purchase or not, based on such considerations as: does it have a CE mark? Are spares available?

7. On arrival of equipment all documents are checked to being complete and the equipment supplied agrees with the order details. If not, the equipment is held as awaiting acceptance and the matter investigated.

8. All equipment received for acceptance shall be subject to goods inwards procedure.

9. The EME/X-Ray Section X-Ray technician performs "in house" acceptance tests based on TRS 89 and STB6A/85/15 to provide baseline readings for subsequent repair/service tasks. All results obtained are recorded and retained for later use.

10. This procedure is also followed for equipment that the department maintains in the private sector.

11. All tools/test equipment used to carry out acceptance checks shall be in good condition and have a valid calibration certificate where required.

12. In cases where equipment fails the acceptance tests, it is returned to the Supplies Department and a reject form is completed detailing points of non-compliance.

13. At all times after delivery to the department the status of the equipment shall be easily ascertained by reference to the status label, which is attached on delivery.

14. Acceptance records are retained for the life of the equipment.

Procedure - Repairs

1. On receipt of a repair/service request a task sheet shall be made out.

2. The Medical Engineering Manager shall allocate a priority of response as below:
    1. Immediate
    2. As soon as possible

3. If a response time is quoted in the relevant contract with the customer then the department shall respond within that stated time.

4. On collection/receipt of the equipment to be repaired the technician in charge shall attach a status label to the equipment and initial the relevant box to indicate its status. This label stays attached to the equipment throughout the repair period. In the case of fixed equipment, e.g. X-Ray plant, a sign shall be hung on the room door to indicate that a repair is in progress.

5. Equipment shall not be modified without the written consent of the equipment manufacturer. Any such modifications shall be documented on a task sheet and subsequently fed back in the equipment history on the department computer.

6. Prior to signing off a job as complete the technician shall check if there are any of the following outstanding, and if so, execute them as required:

    a. Safety action bulletins
    b. Hazard notices
    c. Manufacturers' notices

7. Any equipment that is contaminated or possibly contaminated shall not be worked on until such time as it has been decontaminated.

8. On completion of a repair the task sheet is completed and the status label signed off. A ‘user warning’ label is attached where required, prior to delivery to the client.

9. Equipment not for immediate dispatch is put in to the tasks out area.

10. Equipment found to be not repairable will be dealt with in accordance with section QP22, Condemning Procedure.

11. Due to the diverse nature of X-Ray equipment and its associated maintenance, the Chief Diagnostic Imaging Equipment Technologist has a different system for recording corrective maintenance tasks. No ‘paper’ task sheet is raised. Task description/results are stored digitally in a spreadsheet, maintained by the Chief Diagnostic Imaging Equipment Technologist, and are not fed back into the EME computer system. Additionally, each X-Ray room contains a logbook where all corrective maintenance tasks are recorded after they have been carried out. The logbooks provide a ‘hard copy’ back up for the information held digitally.

<u>Planned Preventative Maintenance</u>

1. Planned Preventative Maintenance (PPM) job lists are generated on a weekly basis by the computer database.

2. Frequency of PPM is governed by:

    a. Client requirements
    b. Manufacturers recommendations

3. PPM content is based on manufacturer's recommendations, but shall as a minimum always include an electrical safety check as in IEC60601-

3. Test results are recorded on the PPM job list which is fed back to the computer on completion of the schedule. Note: See QP20 para.9 for Chief Diagnostic Imaging Equipment Technologist procedures.

ANTI-STATIC WORKSTATIONS CALIBRATION PROCEDURE

1. Calibration interval, 6 months

2. Visually check all parts of the workstation for damage and replace any damaged parts.

3. Connect the workstation to earth by the normal method.

4. Using a "Megger" measure, on the 500V scale, continuity between various locations on the mat and earth. Note the results.

5. Connect the wrist strap to the mat earth stud. Measure with the "Megger" between wrist strap and earth. Note the results.

6. If the values are within the specification then attach a *Calibrated* label.

7. If the values are not within specification then attach a *Do Not Use* label and remove from use. Inform the Medical Engineering Manager.

8. All test results are to be entered on the task sheet.

9. All test equipment used must bear a valid Calibrated label.

Specification
Mat: 100 K ohm to 1 M ohm
Straps: 1 M ohm $\pm$ 20%

(Specification for resistance values obtained from RS components manual February 1990 - February 1991, page 1154, Anti-static Stations.)

INSPECTION, MEASURING AND TEST EQUIPMENT

1. The accuracy of any measurements taken to establish the compliance, or otherwise, of a product, is central to the quality process and as such, the integrity of the measuring equipment is vital. For this reason, all measuring and test equipment is calibrated to ensure its accuracy and reliability. The following procedures have been established to this end.

2. Individual technicians are responsible for ensuring that the test equipment is suitable for the intended purpose and is within its calibration date where applicable, and to bring to the attention of the Medical Engineering Manager or Chief Diagnostic Imaging Equipment Technologist any deficiencies. It is the responsibility of the Medical Engineering Manager and Chief Diagnostic Imaging Equipment Technologist to ensure the procedures are operated correctly. The Quality Manager will regularly review the system.

3. In general an outside calibration agency is used to calibrate all necessary inspection and test equipment. It is the responsibility of the Quality Manager to ensure the company chosen is competent to calibrate to the required accuracy.

4. Any item of inspection or test equipment received by the department is subject to normal goods inwards procedure. On acceptance, the equipment will be returned to store ensuring it bears an accurate calibration-due label. A valid calibration certificate will be obtained for each piece of equipment.

5. All items of inspection test equipment are allocated a unique asset register number that is marked on the equipment with an asset label. Each asset is entered onto the department database system. This records details of all items requiring periodic calibration.

6. Each item of inspection/test equipment entered on the computer system has a history file allocated to it. In this file all work history is recorded and easily retrievable. e.g. Calibration dates, results, etc.

7. The PPM schedule will show when the next recalibration is due. The completed PPM printout is the master document for calibration control purposes.

8. PPM schedules are reviewed monthly to identify such items due for calibration the following month. These items, together with any faulty/suspect ones, are made available for recalibration on the required date. All calibration certificates are retained and brief details entered on the history file.

9. In-house Calibration will be carried out by suitably skilled technicians following written procedures detailing the calibration method, equipment required, etc and any special environmental conditions which are required. Calibration records shall be kept and will be retained for the life of the equipment they relate to.

10. Sub-contractors who undertake calibration services for the department shall be chosen by the Quality Manager, and shall have NAMAS accreditation. Suppliers on the sub-standard list shall not be used.

11. All inspection test equipment, when not in use, will be stored on workshop racks in a suitable temperature-controlled environment.

12. All aspects of calibration procedure shall be periodically reviewed. Calibration intervals might be altered to suit greater/lesser usage, extra storage space might be required due to greater numbers, etc.

ELECTRONIC EQUIPMENT CALIBRATION PROCEDURE

1. Each item to be calibrated is allocated a calibration interval, i.e. the time between successive calibrations. This is determined by type of instrument usage, etc.

2. Calibration intervals are decided after discussion between the Medical Engineering Manager/ Chief Diagnostic Imaging Equipment Technologist and the Quality Manager, and consideration of the manufacturer's recommendations.

3. The normal calibration interval is 12 months, unless stated differently. See table 1.

4. The interval may be amended after consultation at a review meeting, due to changes in criteria, e.g. manufacturer's specification.

5. A task sheet is raised for each piece of equipment to be calibrated both "in-house" and externally.

6. Returned equipment from external agency calibration shall be subject to goods inward procedure.

7. Calibration certificates are required in all cases and are filed.

8. Any equipment marked ‘Not Calibrated or for indication only’ shall be checked prior to each use.

9. All inspection, test equipment shall bear a label to indicate its current status, *e.g*. ‘Calibration next due . . . . .’

TABLE 1 CALIBRATION INTERVALS

Equipment	Interval
Anti-static workstations	6 months
All other equipment	12 months

PROCEDURE: INTERNAL CALIBRATION

1. Certain equipment is able to be calibrated by department staff. The Quality Manager will be the judge as to which items are suitable for this procedure.

2. The calibration procedure must be established and documented prior to adoption.

3. Details of the calibration results shall be entered on the task sheet.

4. Only suitably trained technicians shall be used for calibration duties.

PROCEDURE: EXTERNAL CALIBRATION

1. The following procedure is used when the department sends equipment to external calibration agencies.

2. Equipment due for calibration is identified by the on going PPM schedule.

3. Equipment identified is made available for collection by the calibration agency.

4. A task sheet is raised for each item, and an order generated to cover the work.

5. On return, the equipment is subject to normal goods inward inspection.

6. Check for clear calibration label.

7. Clear all relevant paperwork task sheets orders, etc.

SUB-CONTRACT SPECIFICATION

1. Included in the requirements of the calibration agency shall be:

    a. All equipment must be calibrated traceable to national standards.

    b. Supply a calibration certificate per item.

    c. Supply calibration results to the department, these are to be retained for the life of the equipment.

    d. On completion of calibration affix a label stating calibration date and when due next.